REMARKS

This election is responsive to the Office Action dated December 8, 2005, the period for response being extended to April 10, 2006 (April 8th falling on a Saturday) by a Petition for Three Month's Extension filed herewith.

Basically, the Restriction Requirement is directed to claims which had been canceled by Preliminary Amendment.

The present invention is based on the discovery of an indicator associated with disorders characterized by abnormal cell proliferation.

The present invention is a pioneering invention. Applicant discovered a new pathway of metastasis, discovered an indicator reliably associated with this new pathway, and as a result, made available a novel test for detection of cancer development at an early stage. Applicant is entitled to broad protection.

By way of analogy, the present invention can be compared to discovering that a forest fire can be detected from a great distance by detecting a specific indicator - smoke. It does not matter whether the naked eye, binoculars, a telescope, or a video camera is used to detect the smoke – the tools are not the invention. It does not matter whether the fire is a meadow fire, a brush fire, a tree fire, or a house fire – the type of fire is not the invention. The invention is based on the discovery that a specific indicator is associated with a certain condition, and that by looking for this indicator, the condition can be detected early, allowing early intervention (be it a forest fire or a disorder characterized by abnormal cell proliferation).

Turning to the claims of the Preliminary Amendment, in an effort to expedite examination, Applicants submit that these claims can be classified into six classes:

I. Claims 34-50 directed to a method of detection of disorders characterized by abnormal cell proliferation in an individual, comprising detecting human transketolase like-1 gene in a biological sample, and assessing diagnosis on the basis of the results.

II. **Claims 51-53**, directed to a test kit.

III. **Claims 54-60**, directed to method for treating disorders characterized by abnormal proliferation of cells based on the administration of a pharmaceutical composition containing a human transketolase like-1 gene or gene product in a pharmaceutical acceptable form.

IV. **Claim 61**, directed to a method for identifying and obtaining a drug candidate for therapy of tumors of the colon, the lung, the pancreas or the stomach.

V. **Claim 62**, directed to a pharmaceutical composition for the treatment of tumors of the colon, the lung, the pancreas or the stomach.

VI. **Claims 63 and 64**, directed to a method for rational tumor management.

Applicants respectfully elect for examination Group I, and respectfully submit that Group IV should be combined into Group I.

That is, Group I is directed to a method for detection of disorders characterized by abnormal cell proliferation in an individual. Group IV is directed to a method for identifying a drug candidate for therapy, wherein the diagnostic method and the medical condition are those of Group I.

Should the Examiner require **election of a species** within Group I for initial examination, Applicants elect the species of Claim 41, the method according to claim 34, wherein the detection of the expression of the human transketolase like-1 gene is carried out on a **nucleic acid level**.

Finally, Applicants submit that the present application is a national stage entry of a prior International Application. Under the implementing guidelines set forth in MPEP 1850, the PCT standards, not the US standards, apply in determination of unity, and there should be no difference between the determination of the groups of inventions as set forth in the International Search Report and the national stage application.

According to MPEP 1850 implementing guidelines: "Because restriction practice of this national stage application is determined under unity of invention principles, restriction practice under 35 U.S.C. §121 is not applicable to this national stage application. Any international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (PCT Article 3(4)(iii) and 17(3)(a), PCT Rule 3.1, and 37 CFR § 1.475). Observance of this requirement is checked by the International Searching Authority and may be relevant in the national (or regional) phase.

Therefore, when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, **and during the national stage as a Designated or Elected Office under 35 U.S.C. 371,** PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. No change was

made in restriction practice in United States national applications filed under 35 U.S.C. 111 outside the PCT." (one paragraph omitted, emphasis added)

Accordingly, the issue of unity having been previously considered and decided, Applicants respectfully request that the restriction requirement in the present case be amended to correspond with the determination of unity of invention of record.

Election of Species

Next, the Examiner requires Applicants to elect

- a species of **cancer** and
- a species of **tumor**.

Applicants elect colon cancer and colon tumor, with the understanding that as these species are found allowable, additional species will be examined for allowance.

Entry and favorable consideration are requested.

Respectfully submitted,

Date: **April 10, 2006**

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U.S. Application No.: 10/511,813
RESPONSE TO RESTRICTION REQUIREMENT
SECOND PRELIMINARY AMENDMENT Attorney Docket: 4007.008

CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing RESPONSE TO RESTRICTION REQUIREMENT/SECOND PRELIMINARY AMENDMENT for U.S. Application No. 10/511,813 filed October 19, 2004 is being deposited in via facsimile to 571.273.8300, United States Patent and Trademark Office on **April 10, 2006.**

The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 50-0951.

Stephan A. Pendorf